

RELATORS LINNETTE SUN’S AND GREG HAMILTON’S MEMORANDUM
OF OPPOSITION TO BAXTER HEALTHCARE CORPORATION’S
PARTIAL MOTION TO DISMISS

I. INTRODUCTION

Defendant Baxter Healthcare Corporation's (Baxter) partial motion to dismiss should be denied. Baxter argues that the Court lacks jurisdiction over Relators' claims regarding Baxter's hemophilia drug Recombinate based on the first to file bar of the False Claims Act (FCA). 31 USC §3730 (b)(5). This first to file bar does not apply, as Relators' Recombinate allegations are not based on the same essential facts as those alleged in the prior filed Ven-A-Care complaint.

Defendants also argue that Relator Hamilton should be dismissed from the case since he only qualifies as original source as to Recombinate. As above, Relators' Recombinate claims should not be dismissed. Hamilton has provided direct and independent information regarding a specific AWP fraud scheme regarding Recombinate. As such he should remain a party to this action.

II. FACTS

A. The Sun/Hamilton Complaint

Relators Sun and Hamilton filed their original complaint in April 2005. This complaint alleges a specific scheme by Baxter to defraud federal healthcare programs. The Sun/Hamilton complaint describes in detail Baxter's refusal to provide Wholesale Acquisition Cost (WAC) to First Databank (FDB), in order to inflate prices and cause overpayments by Medicaid. Although this complaint has been amended twice, the essential allegations regarding Baxter's fraudulent scheme have remained unchanged.

B. Ven-A-Care complaint

In 1995, Ven-A-Care of the Florida Keys Inc. filed its original complaint alleging AWP fraud against a multitude of drug companies, including Baxter. Their Fourth Amended complaint, the operative complaint at the time Sun and Hamilton filed their case, was filed in 2002. Ven-A-Care's Fourth Amended Complaint alleges that a long list of drug companies were inflating AWP and reporting it either directly to Medicare/Medicaid or to a reporting agency such as FDB. Ven-A-Care never anything remotely like the specific fraudulent scheme that is at the heart of the allegations in the Sun/Hamilton case.

III. ARGUMENT

A. Relators's Sun/Hamilton's Claims Regarding Recombinate Are Not Barred by the First-to-file Provision of the FCA Because They Are Not Based on the Same Essential Facts as the Prior Ven-A-Care Complaint.

31 USC §3730 (b)(5) states that : “When a person brings an action under this subsection, no person other than the Government may intervene or bring a related action based on the facts underlying the pending action.” “All courts that have addressed the issue have interpreted §3730 (b)(5) to bar ‘a later allegation [if it] states all the essential facts of a previously-filed claim’, or ‘the same elements of a fraud described in an earlier suit’”. *US ex rel. Duxbury v. Ortho Biotech Products*, 579 F. 3d 13 at 33, (1st Cir., 2009) quoting *US ex rel. LaCorte v. SmithKline Beecham Clinical Labs Inc.*, 149 F. 3d 227, at 232-33 (3d Cir., 1998). Here, the Sun/Hamilton complaint alleges Baxter engaged in a specific fraudulent scheme that is not based on the same essential facts alleged in the Ven-A-Care complaint.

The Ven-A-Care complaint is an omnibus complaint that alleges at least four different kinds of possible misrepresentations in cost and price reporting to Medicare and Medicaid by multiple drug companies. Baxter is specifically mentioned in two paragraphs (Section 14) of this complaint. *Ven-A-Care 4AC ¶¶ 177-178*. These paragraphs allege quite generally that Baxter “knowingly ma[de] false or fraudulent representations about prices and costs of drugs...which [it] knew would be utilized by Medicare/Medicaid in paying or approving claims for such drugs and using the Spread as a financial inducement to increase sales of [Baxter’s] drugs” *Ven-A-Care 4AC ¶177*. In addition, this section also alleges that Baxter “knowingly caused its false or fraudulent price and cost representations to be published in....FDB’s Automated Services...and submitted same to Medicare/Medicaid...” Recombinate is listed in the attached Exhibit 6, as one of a number of drugs that Baxter “knowingly caused Medicare/Medicaid to pay falsely inflated reimbursement amounts by reporting falsely inflated drug costs and prices” *Id.*

These two paragraphs allege the general outlines of a scheme by Baxter to falsely report AWP or Direct Price to FDB in order to create a spread and induce use of many of its drugs, including Recombinate. The Sun/Hamilton complaint on the other hand details the essential elements of a specific fraudulent scheme put into place by Baxter, and Baxter alone, after FDB entered into an agreement with the United States Department of Justice that forbade it from simply reporting AWP provided by manufacturers such as Baxter.

The Ven-A-Care complaint also alleges that, as part of an attempt to frustrate OIG and HHS efforts to determine the reasonableness of Medicare and Medicaid pricing, that “[s]ome of the Defendants make representations of cost and price in terms of "List Price," "Wholesale Net," Direct Price "DP" or "DIRP," or Wholesaler Acquisition Costs, "WAC" to which Medical

Economics and First DataBank apply an industry average mark-up and establish an AWP.”

(emphasis added.) *Ven-A-Care 4AC* ¶161b. The complaint does not specify that Baxter did this. Nor does ¶161b suggest which of the several different types of price reporting fraud it lists Baxter may have engaged in. (In fact, it is impossible to tell from this or the previously cited paragraphs exactly what Baxter *had* done to misreport the price of Recombinate.) Relators’ complaint alleges a specific scheme on Baxter’s part to willfully report List Price only despite FDB’s exhortations that WAC be provided as required by the consent decree with Department of Justice.

Until 2000, reporting companies such as FDB reported AWP directly as claimed by the drug manufacturers. In May 2000, FDB and the DOJ entered into a consent decree that required FDB to instead report AWP on the basis of market prices. *Sun/Hamilton Second Amended Complaint (S/H 2AC)* ¶25. FDB took the WAC reported by the drug manufacturer, and multiplied it by 1.25 in order to calculate AWP. *Id* at ¶26. Baxter refused to report the WAC for Recombinate to FDB as it was supposed to; instead, it reported the List Price (probably charged to its charge-back wholesalers to FDB to use as a basis for calculating AWP. The List Price is significantly higher than the actual WAC, as charge-back wholesalers make up a very small percentage of Baxter’s market for biologics and as such do not affect sales. Charge-back wholesalers are not offered the same pricing incentives as non charge-back wholesalers that make up the bulk of the market. *Id* at ¶¶ 31-32.

Baxter in fact refused to provide its WAC for Recombinate despite FDB's repeated requests and warnings that it would be forced to use the LP provided as WAC and calculate AWP from this price. *S/H 2AC* ¶40. Therefore FDB used the LP provide by Baxter as WAC, multiplied it by 1.25 to get a greatly inflated AWP. *Id* ¶41.

The essential facts of the fraudulent scheme alleged by the Sun/Hamilton relators are completely different from the essential facts that underlie the Ven-A Care complaint. According to Ven-A-Care's Fourth Amended Complaint, Baxter *might* have misreported it's list price. Or it *might* have misreported it's Direct Price. Or it *might* have misreported its WAC. Or it *might* have misreported its wholesale net. The record simply does not support Baxter's claim that Sun and Hamilton's specific allegations regarding how one drug was handled after FDB entered into the consent decree were presaged by the far more general Ven-A-Care claims. In *Duxbury*, *supra*, the First Circuit held that the first complaint, which contained three paragraphs generally alleging that defendants used cash payments to induce off-label use of their drug, did not bar the second complaint which alleged a detailed promotional scheme to encourage off-label use. The first complaint did not bar the second, because it did not "encompass the other allegations contained in the [second complaint] concerning [defendant's] 'off label promotion'", and therefore did not "allege the 'essential facts' of the 'off-label' promotion scheme contained in the [second complaint]." *Duxbury* at 33. The same is true of Ven-A Care's complaint as compared with Sun/Hamilton's complaint. Sun/Hamilton discloses Baxter's insistence, after the 2000 consent decree, on providing LP and willfully withholding WAC from FDB in order to artificially inflate the reported AWP; the Ven-A Care complaint merely contains a few paragraphs that state that Baxter knowingly reported false prices and costs to Medicare/Medicaid

and FDB and references a list of different types of prices that were provided to FDB for mark-up. S/H 2AC ¶¶31-41, vs. Venacare 4AC ¶161, 161b. The Ven-A-Care complaint does not encompass the Sun/Hamilton allegations. The Sun/Hamilton complaint is therefore not barred by §3730 (b)(5).

In *US ex rel. Hutcheson v. Blackstone Medical*, 694 F. Supp. 2d 48 (D. Mass, 2010), the court held that a prior complaint did not bar a subsequent one where the second complaint contained additional allegations detailing essential elements of a fraudulent scheme that the first complaint did not. “The allegations contained in the Hutcheson complaint...are more than simply ‘details’, but essential elements of a nationwide fraudulent scheme. The Hutcheson complaint is not barred therefore, because it does not allege ‘the same elements of fraud described in an earlier suit.’” *Hutcheson* at 59. *Rev’d on other grounds*, No. 10-1505, 2011 U.S. App. Lexis 10972 (1st Cir. June 1, 2011); 2011 WL 2150191 (1st Cir. June 1, 2011) and *U.S. ex rel Westmoreland v. Amgen, Inc.*, 707 F.Supp. 2d 123 (D. Mass. 2010) *aff’d in part and rev’d in part on other grounds*, 2011 U.S. App. Lexis 15036, (1st Cir. July 22, 2011), 2011 WL 2937420 (1st Cir. July 22, 2011).

This Court, in its March 25, 2010 Order, Dkt. No. 2008, acknowledges that one essential element of the fraudulent scheme alleged by Sun/Hamilton is Baxter’s reporting “only misleading ‘list sales prices’ to FDB, specifically for Recombinate, even though Baxter knew that FDB needed Baxter to report a WAC and would be forced to rely on Baxter’s ‘list sales price’ if Baxter continued to refuse to report anything else.” *Id.*, at pp. 9-10. Since this “essential element of the fraudulent scheme” is not in the prior Ven-A Care complaint the Sun/Hamilton complaint is not barred by the first-to file rule.

B. Since Sun/Hamilton's claims regarding Recombinate should not be barred by the First-to File provision of the FCA, Hamilton should not be dismissed as Relator.

This Court has already determined, and Baxter acknowledges, that Hamilton is as an original source for the Recombinate claims. March 25, 2010 Order, p. 12, Dkt. No. 2008.

Baxter nonetheless argues that Hamilton should be dismissed based on *US ex rel. Folliard v. CDW Technology Services*, 722 F Supp 2d 37 (DDC, 2010), which states that “[relator (who was subsequently dismissed as a result of this holding)] never worked for the defendants, and his complaint contained no ‘insider’ information that a DOJ attorney who was already investigating the [first-filed] complaint could not have learned” *Id.* at 43. This is merely a disguised effort to relitigate Hamilton’s status as an original source. The Folliard analysis does not even apply to Hamilton. Although it is true that Hamilton never worked for Baxter, it was through his employment at Express Scripts that he gained insider knowledge of Baxter’s practices manipulation of its reporting to FDB. Because of Hamilton’s ongoing business relationships, he was contacted by Kay Morgan of FDB and told about Baxter’s refusal to report anything but list price to FDB. GH Deposition pp.43-46 (Rajaram Decla, Exh. A). This information is an essential element of the fraud and was not disclosed by the previous Ven-A-Care complaint. Nothing in Ven-A-Care’s broad-brush allegations suggest that the Government would have found this post-2000, extremely narrow, extremely specific fraud.

Although Hamilton never actually worked for Baxter, he was still an “insider” within the industry, and as such, privy to “insider information” regarding pricing of Baxter’s products.

While he was employed with Express Scripts, Hamilton held numerous meetings with Baxter regarding the “pricing of several of the Baxter products discussed in the Complaint”, including Advate. GH Deposition, 89-98 (Rajaram Decla. Exhibit “B”).

Given Hamilton’s insider knowledge (which we do not concede is a statutory requirement), and given the highly specific and allegations which may well have gone undetected, his situation is unlike that of the *Folliard* relator, and he ought not precluded by the first-to file bar.

IV. CONCLUSION

The Sun/Hamilton allegations regarding Recombinate are not barred by 31 USC §3730 (b)(5). Because the Recombinate allegations are not barred, Hamilton should not be dismissed from the case.

Respectfully submitted,

LAW OFFICE OF MARK ALLEN KLEIMAN

Dated: August 11, 2011

By: /s/ Pooja Rajaram

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DECLARATION OF POOJA RAJARAM

I, POOJA RAJARAM, hereby declare as follows:

I am an attorney duly licensed to practice before all courts in the State of California. I am a member of the Law Offices of Mark Allen Kleiman and am one of the attorneys of record for relators herein. If called upon to do so I could and would testify competently to the following based upon firsthand knowledge:

1. Attached hereto as Exhibit "A" is a true and correct copy of pages 43-46 of the January 21, 2010 deposition of Greg Hamilton.

2. Attached hereto as Exhibit "B" is a true and correct copy of pages 89-98 of the January 21, 2010 deposition of Greg Hamilton.

I declare under penalty of perjury of the laws of the State of California that the foregoing is true and correct.

Executed this 11th day of September, 2011, in Venice, California.

/s/ Pooja Rajaram

POOJA RAJARAM

CERTIFICATION OF SERVICE

I hereby certify that a true and correct copy of the foregoing **RELATORS LINNETTE
SUN'S AND GREG HAMILTON'S MEMORANDUM OF OPPOSITION TO BAXTER
HEALTHCARE CORPORATION'S PARTIAL MOTION TO DISMISS**
to be delivered by electronic service via LexisNexis File & Serve on was served on all counsel of
record by electronic service on August 11, 2011.

/s/ Pooja Rajaram
POOJA RAJARAM